

Claim 91 has been redrafted to include, in addition to the elements recited in the originally filed Claim 26, elements of original Claims 27 and 32. In addition, present Claim 91 further recites that the phospholipid is present in the particles in an amount of at least about 10 weight percent. Specific support for the amount of phospholipid present in the particles is found at page 10, line 30 of the written description.

Claim 70 has been redrafted to include the elements of original Claims 1, 2, 4 and 7. Present Claim 90 is directed to peptides and is similar to the format of present Claim 70. Claim 109 has been redrafted to include the elements of original Claims 26, 27, 29 and 32.

Newly submitted dependent claims are similar to those originally filed.

The remainder of this Reply is set forth under appropriate subheadings for the convenience of the Examiner.

Rejection of Claims 1-9, 13-18, 22-34, 38-42 and 46-49 Under 35 U.S.C. § 102(b)

Claims 1-9, 13-18, 22-34, 38-42 and 46-49 are rejected under 35 U.S.C. § 102(b) as anticipated by WO 91/16882 to Durrani *et al.*

Applicants have cancelled the originally filed claims and submit new Claims 50-127 which have been drafted to more particularly point out and distinctly claim that which Applicants regard as their invention. Newly added Claims 50-127 are directed to a method for producing spray dried particles having improved stability of a protein (or a peptide) wherein the particles consist essentially of the protein (or peptide) and a phospholipid. Claims 50-69 and 91-108 recite particles wherein the phospholipid is present in the particles in an amount of at least 10%. Claims 70-90 and 109-127 recite particles wherein the phospholipid is endogenous to the lung.

Applicants respectfully submit that present Claims 50-127 are directed to subject matter not embraced by the teachings of the cited reference. Accordingly, it is respectfully submitted that present Claims 50-127 meet the requirements of 35 U.S.C. § 102(b) in view of Durani *et al.*

Rejection of Claims 1-49 Under 35 U.S.C. § 103(a)

Claims 1-49 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 91/16882 to Durrani *et al.* as applied to Claims 1-9, 13-18, 22-34, 38-42 and 46-49.

As discussed above, Claims 1-49 have been cancelled. It is respectfully submitted that present Claims 50-127 are patentable over Durrani *et al.*

Durani *et al.* neither teaches nor suggests Applicants' invention as presently claimed. The reference neither teaches nor suggests a method of combining a protein (or peptide), a phospholipid and a co-solvent (or organic solvent) to produce particles which consist essentially of the protein and the phospholipid. Applicants respectfully submit that all working examples presented in Durani *et al.* teach particles which include, not a protein (or peptide), but rather albuterol sulfate. Furthermore, all working examples presented in the cited document specifically teach particles which include, in addition to albuterol sulfate and lipid(s), other ingredients. Applicants note, for instance, the presence of the additional ingredient  $\alpha$ -tocopherol in all formulations taught with specificity in the working examples of Durani *et al.* Since at page 9, lines 20-21, the reference describes the antioxidant  $\alpha$ -tocopherol as "a drug-protective and lipid-protective agent", Applicants respectfully submit that Durani *et al.* does not teach, suggest or recognize the possibility of preparing spray dried particles having improved stability of a protein (or peptide) without using compounds such as  $\alpha$ -tocopherol.

With respect to Claims 70-90 and 109-127, Applicants specifically note that the cited document neither teaches nor suggests particles wherein the phospholipid is endogenous to the lung. Applicants note, for instance, that at page 9, lines 3-5, Durani *et al.* states that "[l]ipids typically used in the present invention are egg phosphatidylcholine (EPC) and egg phosphatidylglycerol (EPG)". See also the working examples in the cited document. Therefore, it is Applicants' position that Durani *et al.* does not recognize any advantage and provides no motivation for producing particles wherein the phospholipid is endogenous to the lung.

CONCLUSION

In view of the above amendments and remarks, it is respectfully submitted that the present claims are in condition for allowance. Applicants respectfully request that the rejections be reconsidered and withdrawn and that the application be passed to issue.

If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (781) 861-6240.

Respectfully submitted,

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